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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/788,432	02/27/2004	Aaron D. Peacock	UTR-107X	8113

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EXAMINER	
SALMON, KATHERINE D	

ART UNIT	PAPER NUMBER
1634	

MAIL DATE	DELIVERY MODE
05/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

TA

Office Action Summary	Application No.	Applicant(s)	
	10/788,432	PEACOCK ET AL.	
	Examiner	Art Unit	
	Katherine Salmon	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 February 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,8-14 and 16-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6, 8-14, 16-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This action is in response to papers filed 2/20/2007. Currently Claims 1-6, 8-14, and 16-24 are pending. Claims 7 and 15 have been cancelled.

2. The following rejections for Claims 1-6, 8-14, and 16-24 have been made necessitated by amendment.

3. This action is FINAL.

Withdrawn Objections

4. The objections to the Claims made in Section 2 of the previous office action is moot based on the amendments to the claims.

Withdrawn Rejections

5. The rejections of the claims under 35 USC 112/second paragraph made in section 3 of the previous office action is moot based on amendments to the claims.

6. The rejections of the claims under 35 USC 102(b) as being anticipated by Lytle et al., Elasri et al., and Fathepure et al. made in sections 4-6 of the previous office action is moot based on amendments to the claims.

Rejections Necessitated by Amendment

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-6, 8-14, and 16-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Upon review of the specification, the specification does not appear to provide support for recitation of "into which components of said substrate have been incorporated" as amended in Claim 1 step c and Claim 9 step c. In response of the amendment, applicants point to pages 10 and 12 as providing support for "into which components of said substrate have been incorporated". However, the cited passages teach only the incorporation of isotopes and not the broader concept of any component of the substrate being incorporated.

These amendments to the claims, therefore, constitute new matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1-6, 8-14, 16-19, and 21-23 rejected under 35 U.S.C. 103(a) as being unpatentable over Lytle et al. (Journal of Microbiological Methods Vol. 44 2001 p. 271) in view of Banning et al. (Microbiology 2003 Vol. 149 p. 47) as evidenced by dictionary.com (www.dictionary.com).

With regard to Claims 1 and 9, Lytel et al. teaches adhesion deficient gram-negative colonies were grown in a nitriloacetic acid-free basal salt medium with ^{13}C isotope as the sole carbon source (p. 273 1st column 1st paragraph). Lytel et al. teaches

the cells were grown in a sealed tube (solid support) (p. 273 1st column 1st paragraph). Lytel et al. teaches the cells were grown for 20 minutes, therefore the growth of the bacteria would have created a film of colonies on the solid support (p. 273 1st column 1st paragraph). Lytel et al. teaches detecting of palmitic acid and oleic acid (fatty acids) (biomarkers) (Abstract). Lytel et al. teaches that this detection method can be used to correlate biomarkers (palmitic acid and oleic acid) to in situ bioremediation or subsurface sediments (component of bioremediation pathway) (Abstract). Though Lytel et al. does not specifically teaches that the solid support is sterile, it is obvious that the method of Lytel et al. would use a sterile solid support. Lytel et al. teaches that all glassware was rinsed and heated to remove contamination (p. 270 1st column Materials), however, Lytle et al. does not specifically teaches that the stainless-steel tubing (solid support) was heated to sterilize. It is prima facie obvious to one of skill in the art, however, to sterilize components in which bacteria is grown in order to ensure that containments of the components are not grown instead of the bacteria of study. The skilled artisan would be motivated to sterilize all equipment before an experiment including the solid support in order to ensure that the experiment was detecting the bacteria of interest and to reduce the background containments.

With regard to Claim 2-3 and 10-11, Lytel et al. teaches detection of phospholipids fatty acids (Table 1 p. 274).

With regard to Claims 4-5 and 12-13, Lytel et al. teaches specific fatty acids can be used to trace bacteria (subset of microbial organism) (Abstract and p. 271 1st paragraph).

With regard to Claims 6, 14, 19 and 23, Lytel et al. teaches using ^{13}C labeled bacteria (Abstract).

With regard to Claim 8 and 16, Lytel et al. teaches performing PLFA analysis (p. 276 Results 3.2 Detection of unique negative ion of PLFA).

However, Lytel et al. does not teach contacting a microbial community at a subsurface site or down-well groundwater site.

With regard to Claims 1, 9, 17-18, and 21-22, Banning et al. teaches making biofilms from groundwater sites to detect bacteria in drinking water (abstract). It is noted that dictionary.com defines ground water as "the water beneath the surface of the ground, consisting largely of surface water that has seeped down; water beneath the earth's surface, often between saturated soil and rock, that supplies wells and springs", therefore the term groundwater includes a type of subsurface site.

Therefore, it would have been prima facie obvious to one of skill in the art at the time of the invention to modify the method of determine if active bioremediation activity is occurring as taught by Lytel et al. by using a microbial community at a groundwater site as taught by Banning et al. The ordinary artisan would be motivated to modify the method of Lytel et al. to use a microbial community at a groundwater site as taught by Banning et al. because Banning et al. teaches that groundwater provides a reservoir for pathogenic bacteria observed in drinking water distribution systems (abstract). Banning et al. teaches that the detection of the microbial in a biofilm can make determinations on the potential public health risk of water samples (p. 48 1st column 2nd paragraph).

Response to Arguments

The reply traverses the rejection. The reply asserts Lytle et al. does not teaches using a subsurface site or a groundwater site or using a sterile solid support (p. 9 1st paragraph). These arguments have been thoroughly considered but have not been found persuasive. As discussed above it is obvious to use sterile supports in an experimentation to detect bacteria and Banning et al. provides motivation for using a groundwater site.

10. Claims 1-6, 9-14, 17-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Elasri et al. (Applied and environmental microbiology May 1999 p. 2025) in view of Banning et al. (Microbiology 2003 Vol. 149 p. 47) as evidenced by dictionary.com (www.dictionary.com).

Elasri et al. teaches the response of a *P. aeruginosa* biofilm to stress by using a bioluminescent biosensor that responds to DNA damage (p. 2025 2nd column 2nd paragraph last sentence). With regard to Claim 1 and 9, Elasri et al. teaches P. aerugionsa (microbial flora) cell suspension was covered with strontium chloride solution to form small beads and placed on an electrophoresis tray (solid support) (p. 2025 Materials and methods 1st paragraph and last paragraph). Elasri et al. teaches incubating at room temperature (p. 2025 last paragraph). Elasri et al. teaches measuring the cell count after UV exposure (p. 2026 1st column 1st full paragraph). Elasri et al. teaches correlating the response of *P. aeruginosa* to UV stress (Abstract). Though Elasri et al. does not specifically teaches that the solid support is sterile, it is obvious that the method of Elasri et al. would use a sterile solid support. It is prima facie obvious to one of skill in the art, however, to sterilize components in which bacteria is grown in order to ensure that containments of the components are not grown instead of the bacteria of study. The skilled artisan would be motivated to sterilize all equipment before an experiment including the solid support in order to ensure that the experiment was detecting the bacteria of interest and to reduce the background containments.

With regard to Claims 2-3 and 10-11, Elasri et al. teaches a method using a plasmid contains a fusion of the recA promoter of *P. aerugionsa* to the luxCDABE operon of *V. fischeri* (p. 2025 2nd column Bacterial Strain). Elasri et al. teaches that this plasmid contains the lux operon, which reduces flavin mononucleotide and a long fatty acid aldehyde in the presence of oxygen to emit light (p. 2025 1st column last paragraph). Elasri et al. teaches the reductase complex recycles the fatty acid allowing

autonomous bioluminescence (p. 2025 1st column last paragraph). Therefore, the method of Elasri et al. teaches detection of light from the recycling of fatty acid. The fatty acid can therefore be considered the biomarker which is detected. Claims 4-5 and 12-13, the biomarker (the promoter of P. aerugionsa) is characteristic of a bacterial population (subset of microbial organisms).

With regard to Claim 6, 14, 19, and 23, Elasri et al. teaches using strontium, which is listed in Table 1 of the instant application (p. 2025 Materials and methods last paragraph).

With regard to Claims 20 and 24, Elasri et al. teaches adding alginate to the culture (biofilm) to test if alginate is a nutrient (p. 2027 1st column 1st full paragraph). Elasri et al. teaches using beads of strontium alginate matrix and measuring the nutrient level (alginate level) to determine response to UV C stress (p. 2027 2nd column 1st two full paragraphs).

With regard to Claim 7 and 15, Elasri et al. teaches using a clinical strain of *P. aeruginosa* (p. 2025 2nd column Materials and methods 1st paragraph).
However, Lytel et al. does not teach contacting a microbial community at a subsurface site or down-well groundwater site.

With regard to Claims 1, 9, 17-18, and 21-22, Banning et al. teaches making biofilms from groundwater sites to detect bacteria in drinking water (abstract). It is noted that dictionary.com defines ground water as "the water beneath the surface of the ground, consisting largely of surface water that has seeped down; water beneath the

earth's surface, often between saturated soil and rock, that supplies wells and springs", therefore the term groundwater includes a type of subsurface site.

Therefore, it would have been prima facie obvious to one of skill in the art at the time of the invention to modify the method of determine if active bioremediation activity is occurring as taught by Elasri et al. by using a microbial community at a groundwater site as taught by Banning et al. The ordinary artisan would be motivated to modify the method of Elasri et al. to use a microbial community at a groundwater site as taught by Banning et al. because Banning et al. teaches that groundwater provides a reservoir for pathogenic bacteria observed in drinking water distribution systems (abstract). Banning et al. teaches that the detection of the microbial in a biofilm can make determinations on the potential public health risk of water samples (p. 48 1st column 2nd paragraph).

Response to Arguments

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Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Katherine Salmon whose telephone number is (571) 272-3316. The examiner can normally be reached on Monday-Friday 8AM-430PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Katherine Salmon
Examiner
Art Unit 1634

CARLA J. MYERS
PRIMARY EXAMINER